



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement:**

Activators of Human Pyruvate Kinase to Treat Cancer

**AGENCY:** National Institutes of Health, HHS

**ACTION:** Notice

**SUMMARY:** This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-up Exclusive Evaluation Option License Agreement to TeamedOn International, LLC., a company having a place of business in Rockville, MD, to practice the inventions embodied in the following applications:

1. U.S. Provisional Patent Application No. 61/104,091, filed October 9, 2008  
HHS Ref. No.: E-326-2008/0-US-01  
Titled: Activators of Human Pyruvate Kinase  
Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian- Kang Jiang, and Matthew Boxer (NCATS)
2. PCT Application No. PCT/ US2009/60237, filed October 9, 2009  
HHS Ref. No.: E-326-2008/0-PCT-02  
Titled: Activators of Pyruvate Kinase  
Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian- Kang Jiang, and Matthew Boxer (NCATS)
3. Australian Patent Application No. 2009303335, filed October 9, 2009  
HHS Ref. No.: E-326-2008/0-AU-03

Titled: Activators of Pyruvate Kinase  
 Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian- Kang Jiang, and Matthew Boxer (NCATS)

4. Canadian Patent Application No. 2,740,148, filed October 9, 2009  
 HHS Ref. No.: E-326-2008/0-CA-04  
 Titled: Activators of Pyruvate Kinase  
 Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian- Kang Jiang, and Matthew Boxer (NCATS)
5. European Patent Application No. 09740795.1, filed October 9, 2009  
 HHS Ref. No.: E-326-2008/0-EP-05  
 Titled: Activators of Pyruvate Kinase  
 Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian- Kang Jiang, and Matthew Boxer (NCATS)
6. Japanese Patent Application No. 531221-2011, filed October 9, 2009  
 HHS Ref. No.: E-326-2008/0-JP-06  
 Titled: Activators of Pyruvate Kinase  
 Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian- Kang Jiang, and Matthew Boxer (NCATS)
7. U.S. Patent Application No. 13/123,297, filed October 9, 2009  
 HHS Ref. No.: E-326-2008/0-US-07  
 Titled: Activators of Pyruvate Kinase  
 Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian- Kang Jiang, and Matthew Boxer (NCATS)
8. U.S. Patent Application No. 13/433,656, filed March 29, 2012  
 HHS Ref. No.: E-326-2008/0-US-08  
 Titled: Activators of Pyruvate Kinase  
 Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian- Kang Jiang, and Matthew Boxer (NCATS)

The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-up Exclusive Evaluation Option License Agreement may be worldwide, and the field of use may be limited to “Use of PK-M2 activators for treatment of cancer in humans.”

Upon the expiration or termination of the Start-up Exclusive Evaluation Option License Agreement, TeamedOn International will have the exclusive right to execute a Start-up Exclusive Patent License Agreement which will supersede and replace the Start-up Exclusive Evaluation Option License Agreement, with no greater field of use and territory than granted in the Start-up Exclusive Evaluation Option License Agreement.

**DATE:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

**ADDRESS:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated Start-up Exclusive Evaluation Option License Agreement should be directed to: Suryanarayana Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5020; Facsimile: (301) 402-0220; E-mail: [vepas@mail.nih.gov](mailto:vepas@mail.nih.gov). A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

**SUPPLEMENTARY INFORMATION:** The fetal form of Pyruvate Kinase, called PK-M2, is expressed in all cancer cells but is normally inactive. The products and methods sought in the prospective evaluation option license agreement activate PK-M2 and result

in inhibition of tumor development. This invention relates to products and methods of administering PK-M2 activators of various types and methods of treating cancer and diseases susceptible to PK-M2 activators. The prospective Start-up Exclusive Evaluation Option License Agreement is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective Start-up Exclusive Evaluation Option License Agreement and a subsequent Start-up Exclusive Patent License Agreement may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice, that establishes that the grant of the contemplated Start-up Exclusive Evaluation Option License Agreement would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-up Exclusive Evaluation Option License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

May 1, 2014  
Date

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